Reuse of permanent cardiac pacemakers

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Cardiac pacemakers are part of a growing group of expensive implantable electronic devices; hospitals in which 100 pacemakers are implanted per year must budget over $300 000 for these devices. This cost represents a considerable burden to health care resources. Since the "life-span" of modern pacemakers often exceeds that of the patients who receive them, the recovery and reuse of these devices seems logical. Pacemakers can be resterilized and tested with current hospital procedures. Reuse should be acceptable under Canadian law, but the manner in which the pacemakers are recovered and the patients selected should follow careful guidelines. Every patient should provide written informed consent before receiving a recovered pacemaker. Properly executed, reuse of pacemakers should provide a high level of health care while maintaining or reducing the cost of these devices.

Les stimulateurs cardiaques comptent parmi les appareils électroniques intra-corporels dont le nombre ne cesse d'augmenter et qui coûtent cher. L'hôpital qui en pose au-delà de 100 chaque année dépense plus de 300 000$ à cette fin, ce qui taxe lourdement le budget sanitaire. Le stimulateur cardiaque moderne possédant une "durée de vie" souvent plus grande que celle du sujet chez qui il a été implanté, il est logique de penser à le récupérer et à le réutiliser après stérilisation et vérification selon les méthodes actuellement établies en milieu hospitalier. Si une telle réutilisation est conforme aux lois canadiennes, la manière dont les appareils seront récupérés et la sélection des malades qui les recevront doivent suivre des règles établies avec soin; le consentement éclairé du malade sera obtenu par écrit. Dans ces conditions la réutilisation des stimulateurs permettra de maintenir une haute qualité de soins sans en augmenter le coût, voire même en le diminuant.

Cardiac pacemakers have evolved from simple heart-rate support devices, and their implantation is now common. More complex and expensive physiologic pacemakers have been developed,[1] and newer devices that can recognize and terminate tachycardias are also available. While the indications for implanting cardiac pacemakers are becoming more numerous, other electronic devices are being implanted to pace the diaphragm[2] as well as to stimulate back muscles and the digestive and central nervous systems.[3] Today's pacemakers cost between $2000 and $6000; thus, the annual cost to a hospital in which 100 pacemakers are implanted a year is from $300 000 to $500 000 (depending on the types selected). Large numbers of implantations could severely tax the already strained financial resources of the health care system.

Pacemaker expenditures can be controlled, however, by reducing the number of implantations through peer review,[4] by matching each patient with a carefully selected and appropriate device,[1] by programming pacemakers in such a way as to extend their life-span and by reusing pacemakers. We review the technical, economic and legal ramifications of the last approach.

Rationale

Older types of pacemakers, such as the Medtronic (Minneapolis) model 5973, have an 8-year survival rate of 86%;[5] newer types of pacemakers, if properly programmed and implanted, have a "life expectancy" of over 10 years. However, patients who receive pacemakers often have a much shorter life expectancy. Although patient survival after implantation varies with the population selected for pacing, the 3-year mortality rate can reach 40%.[4] Men of advanced age with congestive heart failure and coronary artery disease are at an even greater risk,[6-11] and among high-risk subgroups, such as patients with coronary artery disease and atrioventricular block, the 3-year mortality rate is 60%.[7] The waste is obvious: implanted pacemakers often have more than 5 years of function left when the patient dies. The extent of this waste depends on the number and cost of the devices, but since patients who die early often had severe heart disease and thus were likely to have received the most sophisticated pacemakers[1] the savings can be expected to be considerable.

In some developing countries the reuse of cardiac pacemakers may be a necessity. Even in developed countries like Canada, restraints on Medicare funding have led to discussions about rationing medical services. Physicians must therefore struggle with their wish to provide state-of-the-art care while staying within the budget; any emotional misgivings about using a recovered device should be viewed against this emerging perspective, particularly in light of the already accepted and useful practice of organ recovery and transplantation.

Longevity of pacemakers and patient selection

Pacemaker longevity depends on

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many factors. When a used pacemaker has been properly selected and tested, its longevity is not necessarily shortened. The replacement rate for devices that have been selected for reuse may not differ significantly from that for new devices. Although a new pacemaker may have a greater battery reserve than a recovered device, which may have already used 20% of its energy, battery reserve is only one of many factors that affect pacemaker longevity. Equally important are pulse amplitude, pulse width, pulse rate and availability of special pacemaker programming clinics to optimize these features. With appropriate programming, for example, power consumption can be cut to less than one quarter of the amount of a nonprogrammable pacemaker. Thus, by purchasing a greater number of nonprogrammable pacemakers instead of reusing the more costly programmable ones, a hospital could, in fact, be wasting the resource and delivering less desirable pacemaker service to its patients.

Manufacturers do not feel that the construction of their pacemakers contraindicates their reuse; in fact, some will refurbish recovered pacemakers for reuse. Most pacemaker manufacturers, though, limit their warranties to the first patient. It is therefore preferable to consider such factors as the patient's prognosis and pacer dependency when selecting a pacemaker. The new, manufacturer-guaranteed devices should be reserved for patients with a good prognosis who can be expected to need them longer or for patients who are completely dependent on a pacemaker. Recovered pacemakers are best suited for patients with a short life expectancy and those whose devices are less frequently used.

Economic considerations

The potential economic benefit of reusing pacemakers can be determined by weighing the cost of new devices against the cost of personnel time needed to prepare pacemakers for reuse. The pacemaker can be recovered by the hospital's pathology department, tested by the electronics department and sterilized by the sterilizing service. The hospital would have to establish a protocol for regulating the preparation of pacemakers, keeping records of all measurements and documenting the proper preparation of each device. The use of existing hospital services is therefore minimal; coordination of these activities could be assigned to a nurse in the pacemaker clinic or to another person whose work involves pacemakers. On the basis of 250 implantations a year, Aren and Larsson[12] estimated an annual savings of $180 000 with pacemaker reuse. Furman[13] suggested that pacemaker reuse is both logical and cost-effective. One can expect that as pacemaker reuse becomes accepted and the technique routinely established, the number of devices recovered for reimplantation will increase and the saving realized escalate.

Technical aspects

Testing

Although only the manufacturer can test each component of a pacemaker, hospital personnel can estimate the remaining life of implanted pacemakers and analyse explanted devices to determine whether they are operational. Testing of recovered devices should include a review of the pacemaker's performance before the explantation, as well as electronic analysis to measure pulse amplitude and to detect any failure or damage that may have been caused by the explant procedure or by electric shock.

Pacemakers can be reprogrammed[14] and damaged by transthoracic cardioversion or defibrillation,[15-20] procedures often applied to patients with pacemakers since they frequently have advanced heart disease. Pacemakers sense voltages in the millivolt range, and defibrillators deliver shocks in the kilovolt range (up to 3000 V). In tests carried out in 1969, up to 220 V and currents up to 0.8 A were measured at the inputs of pacemakers implanted in dogs being defibrillated. The test shocks damaged three out of five nonprotected pacemakers.[15] Though because of their size dogs perhaps represent an extreme case, these tests nevertheless prompted manufacturers to equip their pacemakers with circuits guarding specifically against such damage. Medtronic pacemakers, for example, were protected against 500 V and 1 to 2 A of current.[15] In addition, pacemaker manufacturers recommend that defibrillator paddles be kept at least 10 cm away from the pacemaker, probably to minimize the chance of myocardial damage caused by the shunting of large currents from the pacemaker down the electrode into the myocardium.[20] More recently it has been verified that the pacemakers themselves can be damaged by their proximity to the paddles.[19]

Information on the response to defibrillation of the new software-controlled pacemakers is not yet available. It is therefore not advisable to reuse a nonprotected pacemaker or a software-controlled pacemaker that has been recovered from a patient who has undergone cardioversion. Even a protected pacemaker should be subjected to complete electronic testing and specific verification of its input protection circuitry. Modern pacing systems are rarely damaged by electric shocks, so manufacturers no longer recommend that pacemakers routinely be replaced if a patient has received an electric shock. Noninvasive measurements alone can usually detect the gross dysfunction that a damaged pacemaker may reveal during testing after explantation.

Sterilization

Sterilization can destroy all microbial organisms, including highly resistant bacterial endospores,[21] thus protecting both the personnel who handle and the patients who receive recovered pacemakers. Since a pacemaker with nonmetal parts may be difficult to clean and sterilize, the United Kingdom Department of Health and Social Security suggests that all rubber and plastic parts be removed from a recovered pacemaker before sterilization.[22] Although the plastic and rubber parts of some pacemakers, such as the Biotronik (Berlin) Bio-loc devices, are easy to remove, and although the silicone rubber in others (e.g., those of Telectronics [Lone Cove, Australia]) can be replaced by the manufacturer, the removal of all nonmetal parts

is generally difficult and probably not cost-effective. The methods we will describe clean and sterilize the pacemakers satisfactorily without stripping them of all their plastic and rubber parts.

Sterilization can be achieved with steam autoclaving and nuclear radiation or with high-level disinfectants that kill bacteria, fungi, viruses[23] and bacterial spores. Such disinfectants include glutaraldehyde, formaldehyde with alcohol, and stabilized hydrogen peroxide,[21] as well as ethylene oxide.[21,24,25] Because a pacemaker's electronic components could be damaged by the high temperature in the autoclave or by nuclear radiation, manufacturers and hospitals sterilize both new and contaminated pacemakers with these high-level disinfectants. Recovered pacemakers have been adequately sterilized in formaldehyde[12] and glutaraldehyde.[26] Some use a low-level disinfectant (dimethylbenzyl ammonium chloride) combined with ethylene oxide,[27] formaldehyde[28,29] and glutaraldehyde.[30] Resterilization with ethylene oxide gas alone has also been reported.[31,32] Despite the variety of resterilization methods, they all include a high-level disinfectant, and no pacemaker-transmitted infections have been reported. Recovered pacemakers that have been properly sterilized are clearly biologically safe for reimplantation.

Legal considerations

Despite the fact that pacemaker reuse has been proven medically safe, the jurisprudence surrounding the procedure cannot be ignored. Medicolegal factors are such that they prompted one author to advise against reuse[33] and another to suggest that recovered pacemakers be sent to Third-World countries.[34]

Legal specifications concerning ownership of a device upon the death of a patient vary from country to country. For instance, Swedish law requires that pacemakers be removed at the time of death (F.H. Schuller: personal communication, 1982), while in Canada pacemakers, although implanted without direct cost to patients, are nevertheless considered the property of the patients or their heirs. Indeed, pacemakers may be removed only if an autopsy is performed or with the consent of the patient's heirs or next of kin or the executor of the patient's estate, according to the legislation of the province.

The reuse of a pacemaker in a manner consistent with accepted medical standards of care and skill should be permissible, provided that the pacemaker can be resterilized and that, in the manufacturer's opinion, no technical factors exist to prevent its reimplantation. To our knowledge, no manufacturer has indicated that the design of its pacemaker contraindicates its reuse. Nevertheless, complications arise from implanting new pacemakers[35] and are therefore to be expected from implanting recovered devices. The cost of litigation by patients who suffer such complications could easily negate any savings in new equipment.

When there are no perceived additional risks of implanting a recovered pacemaker and no specific questions are asked by the patient, the patient probably does not have to be informed that the pacemaker has been recovered; however, it would be safer to provide such information in obtaining informed consent. If a patient asks about the pacemaker or its life-span the questions must be answered. Legal liability for failure to inform the patient should only arise when a person who is aware of the risks involved would not have allowed the operation. *The onus is on the physician to estimate the risks, if any, of reuse and to inform the patient of these risks.* Whether or not the patient could have obtained a new pacemaker when the operation became necessary could be important. When a pacemaker with a long life-span is required, for example, the reuse of a pacemaker with a shorter life-span could present a risk of litigation. The circumstances of each case should, of course, be taken into consideration.

In some countries, such as Sweden, the patient is not informed that the pacemaker has been recovered, but in Canada it would seem prudent to use a consent form that lists the risks of implantation and explains that the type of pacemaker to be used and whether it will be a recovered pacemaker will be decided on the basis of established hospital practice and the clinical judgement of the attending physician.

For both medical and legal reasons the history of each pacemaker, including the length of time it was previously used, any complications that arose during that time, and all the testing and sterilization procedures that have since been carried out, should be recorded. The procedure for pacemaker reuse — obtaining adequate sterilization, testing and informed consent of the patient — should be carefully planned and authorized by the hospital's board of directors.

Throughout this paper we have considered the reimplantation of pacemakers in the hospital system in which the device was recovered, since this is consistent with current hospital practice. Should a third party, neither the original manufacturer nor the hospital, process and resell pacemakers, the issue would become more complicated. Which standard would this party be obliged to respect? Would the third party be a "manufacturer" and therefore subject to the same obligations, or would it create a new manufacturing level, given that it would be using devices that had already been submitted to quality control and were in good working order? A new standard might indeed be required, and until this issue is clarified the feasibility of establishing commercial centres to prepare recovered devices will be in doubt. Clearly the attitude and legal input of the manufacturers will have a significant impact.

Experience

Whereas today's lithium-powered pacemakers are hermetically sealed in stainless steel or titanium containers, the previous generation of mercury/zinc-powered pacemakers were not. Despite the possible sterilization problems that could result from the lack of hermeticity, Havia and Schuller[26] reported on the reimplantation of 50 mercury/zinc pacemakers and found no cases of primary infection, allergic reaction or rejection. Only 1 of the 80 devices reimplanted by Aren and Larsson[12] failed, and no complications from the pacemaker pockets or the pulse generators were reported. Two of

the 80 reused pacemakers were implanted for a third time. Amikam and associates[27] reported their experience with 80 reused pacemakers, among which were some that had previously been removed because of infection. Neither surgical complications nor battery depletion occurred at a rate higher than that expected with new devices. Of the 83 lithium-powered and hermetically sealed pacemakers used by Mond and colleagues[29] 1 was replaced because of battery depletion after 35 months, and another was removed because of an infection in the patient's previously infected pacemaker pocket. Twelve of these devices were implanted for a third time. Primary infections, unusual tissue reactions, hepatitis B and other complications were not observed. Costa and coworkers[30] achieved similar results with 22 reimplanted pacemakers. Currently almost 2000 pacemakers have been reused, with excellent results.[36]

At the Montreal General Hospital 32 pacemakers have been recovered for possible reuse: 10 have been rejected, 1 has been returned to the manufacturer for refurbishing, 6 are being tested and evaluated, and 4 are ready for use. Since the initiation of reimplantation 6 months ago, 11 pacemakers have been reused, at a cost of $150 for replaceable parts and with a saving of $23 000 in new pacemakers. All the pacemakers were prepared according to the protocol shown in Table I. One pocket had to be reopened because the wrong insulating cap had been placed on the set screw of a pacemaker; there was no complication from this corrective procedure. One patient died from cardiogenic shock (unrelated to the pacemaker) 2 weeks after implantation, and the remaining 10 patients are doing well. There have been no infections or malfunctions related to the pacemakers, and the patients have shown a high level of acceptance for the recovered devices.

Conclusions

Health care professionals are increasingly being pressured to reconcile a limited budget with an increasing number of expensive implantable electronic devices. Physicians aware of the impact of such expenditure on health care resources must select appropriate candidates for implantation, optimally program the pacemakers and carefully match the patients with the devices. Pacemaker reuse is one way to reduce the financial pressure on both the physician and the hospital, allowing them to retrieve sophisticated equipment and offer better pacemakers to a greater number of patients. We feel that this method is preferable to either refusing to implant devices in patients with a poor prognosis or using cheaper, less desirable pacemakers. Already practised on a small scale in Canada, pacemaker recovery and reimplantation is routinely undertaken in other countries with high standards of health care.

Table I—Protocol of the Montreal General Hospital for the recovery and reuse of cardiac pacemakers

Reuse criteria
Implanted less than 2 years.
Expected life-span greater than 4 years.
No pre-explantation indication of dysfunction.
Recovery
Remove pacemaker by cutting wires.
Package and protect pacemaker from mechanical shock.
Cleaning
Wear rubber gloves.
Remove and discard wires, caps, boots and sutures, and soak pacemaker in detergent solution (i.e., Buell cleaner liquid no. 444) for 10 minutes. Carefully remove all surface material and clean holes with pipe cleaners.
Soak pacemaker in glutaraldehyde for more than 10 hours. Rinse in water and dry.
Testing
Measure pulse width and voltage.
Measure sensitivity and refractory period.
Measure pulse rate with and without a magnet.
Test programmability.
Test input defibrillation-protection circuit.
Final preparation
Wash pacemaker in detergent, rinse in isopropyl alcohol, blow out passages with air, and dry.
Double-package pacemaker in a gas-permeable envelope and sterilize in ethylene oxide gas at 52 to 55°C with the standard sterilization cycle. Validate the sterilization with standard spores. Ventilate for 30 hours.
Label and store pacemaker in shock-resistant container.
Replace plastic caps and boots at time of implantation.

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References

1. Rosengarten MD, Chiu RCJ: Artificial cardiac stimulation: a current view of physiologic pacemakers. *Can Med Assoc J* 1983; 128: 1377–1380
2. Oakes DD, Wilmot CB, Halverson D et al: Neurogenic respiratory failure: a 5-year experience using implantable phrenic nerve stimulators. *Ann Thorac Surg* 1980; 30: 118–121
3. "Biostimulation 84". International Conference on Biostimulation, Monaco, June 22–23, 1984
4. Chokshi AB, Friedman HS, Malach M et al: Impact of peer review in reduction of permanent pacemaker implantations. *JAMA* 1981; 246: 754–757
5. Bilitch M, Hausser RG, Goldman BS et al: Performance of cardiac pacemaker pulse generators. *Pace* 1984; 7: 311–315
6. Nowlan SP, Crampton RS, McGuire LB et al: Factors influencing survival of patients with permanent cardiac pacemakers. *Ann Surg* 1977; 185: 122–127
7. Otterstad JE, Selmer R, Ström O: Prognosis in cardiac pacing. A comparison between patients with atrioventricular block and sick sinus syndrome. *Acta Med Scand* 1981; 210: 47–52
8. Simon AB, Janz N: Symptomatic bradyarrhythmias in the adult: natural history following ventricular pacemaker implantation. *Pace* 1982; 5: 372–383
9. Hanson JS, Grant ME: Nine-year experience during 1973–1982 with 1,060 pacemakers in 805 patients. *Pace* 1984; 7: 51–62
10. Simon AB, Zloto AE: Symptomatic sinus

node disease: natural history after permanent ventricular pacing. *Pace* 1979; 2: 305–314
11. Alpert MA, Katti SK: Natural history of sinus node dysfunction after permanent implantation. *South Med J* 1982; 75: 1182–1188
12. Aren C, Larsson S: Reuse of lithium cardiac pulse generators. In *Proceedings of the VI World Symposium on Cardiac Pacing*, PACESYMP, Montreal, 1979: chap 39-3
13. Furman S: Reuse of the implanted cardiac pacemaker [E]. *Pace* 1979; 2: 265–266
14. Barold SS, Ong LS, Scovil J et al: Reprogramming of implanted pacemaker following external defibrillation. *Pace* 1978; 1: 515–520
15. Lau FYK, Bilitch M, Wintroub H: Protection of implanted pacemakers from excessive electrical energy of DC shock. *Am J Cardiol* 1969; 23: 244–249
16. Aylward P, Blood R, Tonkin A: Complications of defibrillation with permanent pacemakers in situ. *Pace* 1979; 2: 462–464
17. Furman S: External defibrillation and cardiac pacemakers [E]. *Pace* 1981; 4: 485–486
18. Das G, Eaton J: Pacemaker malfunction following transthoracic countershock. Ibid: 487–490
19. Gould L, Patel S, Gomes GI et al: Pacemaker failure following external defibrillation. Ibid: 575–577
20. Levine PA, Barold SS, Fletcher RD et al: Adverse acute and chronic effects of electrical defibrillation and cardioversion on implanted unipolar cardiac pacing systems. *J Am Coll Cardiol* 1983; 1: 1413–1422
21. Favero MS: Sterilization, disinfection, and antisepsis in the hospital. In Lennette EH, Balows A, Hauser WJ et al (eds): *Manual of Clinical Microbiology*, 3rd ed, Am Soc Microbiol, Washington, 1981: 952–959
22. *Health Notice* (HN[78]60), UK Dept of Health and Social Security, Health Services Supply, branch 5, London, 1978
23. *Hepatitis Surveillance* (Center for Disease Control rep 41), US Dept of Health, Education, and Welfare, Public Health Service, Washington, 1977
24. Kereluk K, Gammon RA: The microbiocidal activity of ethylene oxide. *Dev Ind Microbiol* 1973; 14: 28–41
25. Sidwell RW, Dixon GJ, Westbrook L et al: Procedure for the evaluation of the virucidal effectiveness of an ethylene oxide gas sterilizer. *Appl Microbiol* 1969; 17: 780–796
26. Havia T, Schuller H: The re-use of previously implanted pacemakers. *Scand J Thorac Cardiovasc Surg* 1978; 22: 33–34
27. Amikam KS, Feldman S, Riss E et al: Clinical experience with reused pulse-generators. In *Proceedings of the VI World Symposium on Cardiac Pacing*, PACESYMP, Montreal, 1979: chap 39-1
28. Mond H, Tartaglia S, Cole A et al: The refurbished pulse generator. *Pace* 1980; 3: 311–317
29. Mond H, Cole A, Tartaglia S et al: The refurbished pacemaker [abstr]. *Pace* 1979; 2: A-73
30. Costa R, Moreira L, Pëgo-Fernandes PM et al: Reutilizacão de geradores de marca-passo. *Arq Bras Cardiol* 1983; 40: 317–318
31. Feruglio GA, Pagani T: Recupero e reimplanto del pacemaker. Indagine sui fattori di ordine biologico. *Ital Cardiol* 1978; 8: 315–317
32. Libänskä A, Prüchovä J, Vräna M et al: [Sterilization of cardiostimulators by ethylene oxide and determination of their sterility]. *Cesk Farm* 1972; 21: 7–12
33. Smyth NP: Pulse generator sterilized and reused. *Pace* 1979; 2: 373
34. Harisprasad MK, McClanahan BJ: Reuse of cardiac pacemakers [C]. *N Engl J Med* 1982; 306: 551
35. Goldman BS, MacGregor DC: Management of infected pacemaker systems. *Clin Prog Pacing Electrophysiol* 1984; 2: 220–235
36. Boal B, Escher D, Furman S et al: Report on the Policy Conference on Pacemaker Re-use sponsored by the North American Society of Pacing and Electrophysiology. *Pace* 1985; 8: 161–163